



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



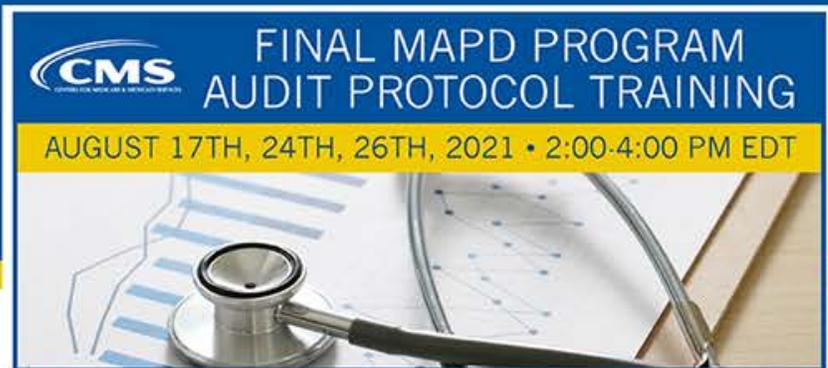
Part D Formulary and Benefit Administration (FA) August 24, 2021

Matthew Guerand

Division of Audit Operations, Medicare Parts C & D Oversight & Enforcement Group, CMS

For Official Federal Government Use Only

This pre-decisional, privileged, and confidential information is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.



Polling Question 1

Let us know who is listening:

- A. Medicare Advantage/Prescription Drug Plan
- B. Independent Auditor
- C. Pharmacy Benefit Manager
- D. CMS Central/Regional Office
- E. Other



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Overview

- FA Program Audit Protocol
 - Audit Elements Tested
 - Method of Evaluation
- FA Program Audit Data Request
 - Review Technical Specifications





FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



FA Program Audit Protocols

- Specifications and tools are for auditing/monitoring activities, not interpreting policy
- Not all data points are used to determine compliance





FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



FA Audit Elements

- Audit Elements Tested
 - Formulary Administration
 - Transition



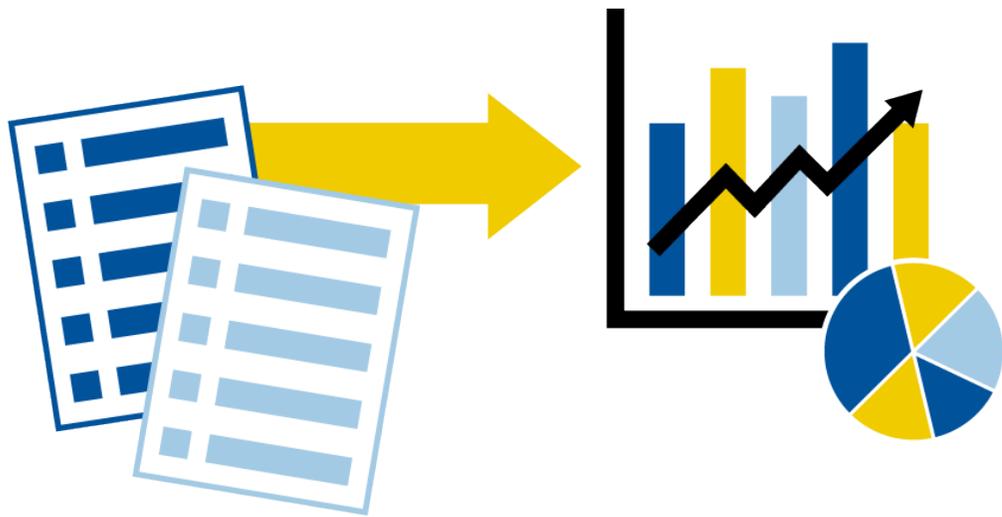


FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Universe Integrity Testing



- CMS will verify accuracy of data within each rejected claims universe submission



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element: Sample Selection



- 30 targeted rejected claims
 - Prior authorization, non-formulary drugs, quantity limit
- Sample set will represent mix of non-protected and protected class drugs claims



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element (1 of 5)

30 SAMPLES

- Claim adjudication process follows CMS approved formulary
- Unapproved utilization management edits do not restrict access
- Appropriate effectuation of authorization records



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element (2 of 5)

30 SAMPLES

- APPROPRIATE ADMINISTRATION OF PRIOR AUTHORIZATION FOR STEP THERAPY FOR PROTECTED CLASS DRUGS

- Claim adjudication process follows CMS approved formulary
- Unapproved utilization management edits do not restrict access
- Appropriate effectuation of authorization records



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element (3 of 5)

30 SAMPLES

- Claim adjudication process follows CMS approved formulary
- Unapproved utilization management edits do not restrict access
- Appropriate effectuation of authorization records

- APPROPRIATE ADMINISTRATION OF PRIOR AUTHORIZATION FOR STEP THERAPY FOR PROTECTED CLASS DRUGS
- SPECIAL REQUIREMENTS FOR LONG TERM CARE DISPENSING



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element (4 of 5)

30 SAMPLES

- Claim adjudication process follows CMS approved formulary
- Unapproved utilization management edits do not restrict access
- Appropriate effectuation of authorization records

- **APPROPRIATE ADMINISTRATION OF PRIOR AUTHORIZATION FOR STEP THERAPY FOR PROTECTED CLASS DRUGS**

- **SPECIAL REQUIREMENTS FOR LONG TERM CARE DISPENSING**

- **CLAIM REJECTIONS BASED ON PRESCRIBER IDENTIFICATION INFORMATION**



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Formulary Administration Element (5 of 5)

30 SAMPLES

- Claim adjudication process follows CMS approved formulary
- Unapproved utilization management edits do not restrict access
- Appropriate effectuation of authorization records

- **APPROPRIATE ADMINISTRATION OF PRIOR AUTHORIZATION FOR STEP THERAPY FOR PROTECTED CLASS DRUGS**

- **SPECIAL REQUIREMENTS FOR LONG TERM CARE DISPENSING**

- **CLAIM REJECTIONS BASED ON PRESCRIBER IDENTIFICATION INFORMATION**

- **PART D DRUG MANAGEMENT PROGRAM REQUIREMENTS:**
 - Care coordination (opioid safety edits)
 - Pharmacy and prescriber limitations
 - 7-day supply limit for initial opioid fills



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT

Transition Element: Sample Selection

Universe Table 2 Continuing Enrollees

≤ 15 claims

- Rejected claims related to cross-year formulary changes
- Between AY and previous CY

Universe Table 2 New Enrollees

≤ 15 claims

- Rejected claims related to formulary administration during transition



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Transition Element

REVIEW THE 30 TARGETED SAMPLES SELECTED

**30
SAMPLES**

Determine
rejection is
appropriate

Identify and
review protected
class rejections
to look for
broader issues

Enrollees and
prescribers
received
appropriate,
timely, and
accurate
transition fill
notices



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Program Audit Data Request



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



RCFA and RCT

Scope of Universe Request and Record Layout Instructions

Rejected Claims Formulary Administration (RCFA)

Table 1

Sponsoring Organizations with:

- < 20,000: 8-week period
- $\geq 20,000 < 500,000$: 4-week period
- $\geq 500,000$: 2-week period

Include all rejected claims with dates of service within universe period

Rejected Claims Transition (RCT)

Table 2

Sponsoring Organizations with:

- < 100,000: January & February of Audit Year
- $\geq 100,000$: January of Audit Year



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



PDE and NE

Scope of Universe Request and Record Layout Instructions

Prescription Drug Event (PDE)	New Enrollee (NE)
<p align="center">Table 3</p>	<p align="center">Table 4</p>
<p>Final action PDEs with dates of service:</p> <ul style="list-style-type: none"> September – December of contract year immediately prior to audit year for all enrollees in Table 2 (RCT) and; Enrollees with effective enrollment dates of November and December of contract year immediately prior to audit year 	<p>< 100,000</p> <ul style="list-style-type: none"> Submit all enrollees with effective enrollment dates of 11/1/previous AY – 2/1/current AY <p>≥ 100,000</p> <ul style="list-style-type: none"> Submit all enrollees with effective enrollment dates of 11/1/previous audit year – 1/1/current audit year

Field Descriptions – Enrollment Effective Date and Effective Disenrollment Date



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



ENROLLMENT EFFECTIVE DATE	EFFECTIVE DISENROLLMENT DATE	NDC
<ul style="list-style-type: none"> • Effective Date of enrollment for enrollee (PBP level) • Enter enrollment date relevant to contract and plan ID of enrollee at time of claim • New Enrollee Record Layout - a separate record should be entered each time an enrollee is enrolled and considered a new enrollee 	<ul style="list-style-type: none"> • Effective date of disenrollment for the enrollee (PBP level) • Enter disenrollment date relevant to contract and Plan ID of enrollee at time of claim • Enter NA if enrollee was not disenrolled 	<ul style="list-style-type: none"> • Aligns with the field description within the CDAG protocol • May be populated as blank when a blank field is submitted by pharmacy or delegate • For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Field Descriptions – NDC

ENROLLMENT EFFECTIVE DATE	EFFECTIVE DISENROLLMENT DATE	NDC
<ul style="list-style-type: none"> • Effective Date of enrollment for enrollee (PBP level) • Enter enrollment date relevant to contract and plan ID of enrollee at time of claim • New Enrollee Record Layout - a separate record should be entered each time an enrollee is enrolled and considered a new enrollee 	<ul style="list-style-type: none"> • Effective date of disenrollment for the enrollee (PBP level) • Enter disenrollment date relevant to contract and Plan ID of enrollee at time of claim • Enter NA if enrollee was not disenrolled 	<ul style="list-style-type: none"> • Aligns with the field description within the CDAG protocol • May be populated as blank when a blank field is submitted by pharmacy or delegate • For multi-ingredient compound claims, populate with the NDC as would be submitted on a paid claim's PDE



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Field Descriptions – Reject Reason and Pharmacy Message

REJECT REASON CODE	PHARMACY MESSAGE
<ul style="list-style-type: none">• Reason code associated with rejected claim<ul style="list-style-type: none">○ All reject codes associated with a claim must be included○ If pharmacy message is generated without a reject reason code: enter <i>NA</i>	<ul style="list-style-type: none">• Pharmacy message associated with reject reason code<ul style="list-style-type: none">○ If reject reason code is generated without a pharmacy message: enter <i>NA</i>



FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Impact Analysis Instructions

Impact Analysis Summary (IAS) Record Layout	Enrollee Impact Analysis (ENR-IA) Record Layout
Tables 1IA	Table 2IA
<ul style="list-style-type: none"> • Noncompliance Synopsis <ul style="list-style-type: none"> ✓ Drugs impacted ✓ Remediation efforts 	<ul style="list-style-type: none"> • Enrollees impacted by noncompliance

- Used for Formulary Administration and Transition

Table 1IA (IAS) and Table 2IA (ENR-IA) Record Layout



- Submit a list of all medications and/or enrollees impacted by the noncompliance
 - Formulary Administration
 - Date of impact analysis request through start date of universe period
 - Transition
 - Date of impact analysis request through January 1st of the current year
 - Late enrollment in previous year (November or December): date new enrollee enrollment date in the previous year





FINAL MAPD PROGRAM AUDIT PROTOCOL TRAINING

AUGUST 17TH, 24TH, 26TH, 2021 • 2:00-4:00 PM EDT



Table 1IA (IAS) Record Layout

- Include all medications impacted by the issue, including those that may not have an associated rejected claim



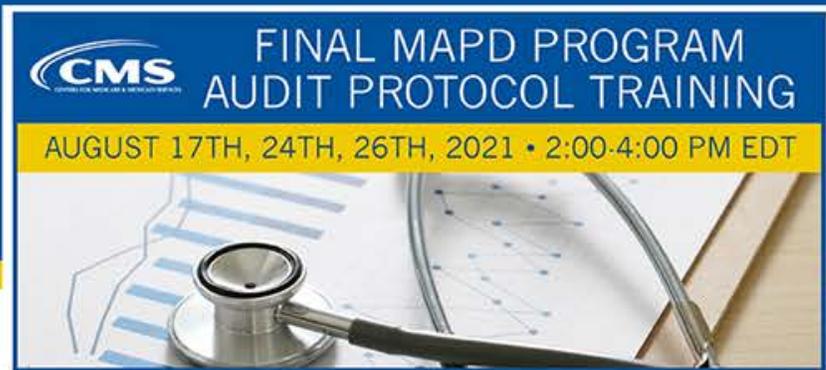


Table 2IA (ENR-IA) Record Layout



- Include the following data for impacted enrollees:
 - Rejected claims affected by the noncompliance
 - Inaccurate records that may not be associated with a rejected claim
 - Include separate entries for each time enrollee experienced an inappropriate rejection at the point of sale as a result of the noncompliance.